

Lawrence J. Gornick (SBN 136290)  
Debra DeCarli (SBN 237642)  
**LEVIN SIMES KAISER & GORNICK LLP**  
44 Montgomery Street, 36<sup>th</sup> Floor  
San Francisco, CA 94104  
Telephone: (415) 646-7160  
Fax: (415) 981-1270  
[lgornick@lskg-law.com](mailto:lgornick@lskg-law.com)  
[ddecarli@lskg-law.com](mailto:ddecarli@lskg-law.com)

Attorneys for Plaintiffs

**UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF CALIFORNIA**

**MEJ**

RICHARD HASKIN, individually and on  
behalf of all others similarly situated,

Plaintiffs,

vs.

MERCK & CO., INC. and SCHERING-  
PLOUGH CORP.

Defendants.

Case No:

**08 0376**  
**CLASS ACTION COMPLAINT AND JURY  
DEMAND**

Plaintiff, RICHARD HASKIN, by and through his undersigned attorneys, **LEVIN SIMES KAISER and GORNICK LLP**, hereby commences this action individually, and on behalf of the Class identified below, and seeks Class status on behalf of himself and the Class as described below.

**NATURE OF THE CASE/OVERVIEW**

1. Plaintiff brings this action on behalf of all persons residing in the State of California who purchased Vytorin<sup>®</sup>. Plaintiff brings this action pursuant to Rule 23 of the Federal Rules of Civil Procedure (hereinafter "F.R.C.P.") to recover compensatory, equitable, and actual and punitive damages, injunctive relief, and attorneys' fees.

2. Plaintiff seeks to represent the following class:

**Vytorin<sup>®</sup> Class:** All citizens, residents, or domiciliaries of the State of California who have purchased Vytorin<sup>®</sup> and such citizens', residents' and domiciliaries'

1 estates, representatives, administrators, spouses, children, relatives and  
2 "significant others" as their heirs or survivors.

3 3. Defendants Merck & Co., Inc. and Schering-Plough Corporation (hereafter  
4 collectively referred to as "Defendants") designed, researched, manufactured, tested, sought approval  
5 by the United States Food and Drug Administration (hereinafter "FDA"), advertised, promoted,  
6 marketed, sold and/or distributed Vytorin<sup>®</sup> for the reduction of total cholesterol, low-dense  
7 lipoprotein (LDL) cholesterol and triglyceride levels while simultaneously raising high dense  
8 lipoprotein cholesterol.

9 4. Vytorin<sup>®</sup> combines Zetia<sup>®</sup>, a cholesterol-lowering agent developed at Schering-Plough  
10 Corporation with Zocor<sup>®</sup>, Merck & Co., Inc.'s cholesterol-lowering medicine.

11 5. Vytorin<sup>®</sup> generates approximately five (5) billion dollars a year in sales for Merck &  
12 Co., Inc. and Schering-Plough Corporation.

13 6. As a result of the defective nature of Vytorin<sup>®</sup>, the drug is ineffective at reducing total  
14 cholesterol, low-dense lipoprotein (LDL) cholesterol and triglyceride levels while simultaneously  
15 raising high-dense lipoprotein cholesterol levels.

16 7. As a result of the defective nature of Vytorin<sup>®</sup>, the drug increases the arterial intima-  
17 media thickness thereby greatly increasing the risk of myocardial infarction and/or cerebral vascular  
18 accidents.

19 8. As a result of the defective nature of Vytorin<sup>®</sup>, the drug increased the fatty plaques in  
20 the arteries including the carotid of the participants in the clinical trial known as ENHANCE.

21 9. As a result of the defective nature of Vytorin<sup>®</sup>, the drug increased the intima-media  
22 thickness (IMT) of the clinical trial participants that used Vytorin<sup>®</sup> as compared to the clinical trial  
23 participants that used Zocor.

24 10. The ENHANCE clinical trials showed that Vytorin<sup>®</sup> was no better at reducing artery  
25 clogging than the older and much less expensive Zocor.

26 11. The ENHANCE clinical trial did not show that Vytorin<sup>®</sup> is any more effective than  
27 Zocor on its own in affecting the rate of atherosclerosis progression.  
28

12. At all times relevant, Defendants misrepresented the safety of Vytorin<sup>®</sup> and negligently designed, manufactured, marketed, advertised, promoted, sold and distributed Vytorin<sup>®</sup> as a safe and effective medication to reduce total cholesterol, low-dense lipoprotein (LDL) cholesterol and triglyceride levels while simultaneously raising high-dense lipoprotein cholesterol levels.

13. At all times relevant, Defendants failed to warn of the dangers of Vytorin<sup>®</sup> including but not limited to the fact that Vytorin<sup>®</sup> increased the intima-media thickness (IMT) of the clinical trial participants that used Vytorin<sup>®</sup> as compared to the clinical trial participants that used Zocor.

14. At all times relevant, Defendants knew, and had reason to know, or should have known, that Vytorin<sup>®</sup> was not efficacious in managing hyperlipidemia thereby defrauding Plaintiff, members of the Plaintiff Class, physicians, patients and the population-at-large while accelerating the advancement of cardiovascular disease (hereinafter "CVD") leading to, in some patients, myocardial infarction and/or cerebral vascular accidents.

15. At all times relevant to this action, Defendants knew, and had reason to know, or should have known, that its representations that Vytorin<sup>®</sup> was safe and effective were materially false and misleading.

16. As a result of the defective nature of Defendants' product, Vytorin<sup>®</sup> fails to control hyperlipidemia thereby placing patients at an increased risk of accelerating or worsening CVD, which could result in myocardial infarction or cerebral vascular accident. Defendants knew, had reason to know, and/or should have known of this tendency and the resulting risk of injuries and deaths, as well as the total lack of efficacy, but failed to warn Plaintiff and all other Plaintiff Class members, and/or their physicians, preventing Plaintiff and Plaintiff Class members, and/or their physicians, and or the medical community from making informed choices about the selection of cholesterol lowering medications.

17. As a result of the defective nature of Defendants' product, Vytorin<sup>®</sup> accelerates the thickening of arterial intima-media hereby placing patients at an increased risk of myocardial infarction or cerebral vascular accident. Defendants knew, had reason to know, and/or should have

1 known of this tendency and the resulting risk of injuries and deaths, but failed to warn Plaintiff and  
2 all other Plaintiff Class members, and/or their physicians, preventing Plaintiff and Plaintiff Class  
3 members, and/or their physicians, and or the medical community from making informed choices  
4 about the selection of cholesterol lowering medications.

5 18. Defendants concealed their knowledge of the defects in their products from the  
6 Plaintiff, all Plaintiff Class members, and/or their physicians, hospitals, and pharmacists.

7 19. Consequently, Plaintiff and all Plaintiff class members seek compensatory damages as  
8 a result of their use of Vytorin®.

9 **JURISDICTION & VENUE**

10 20. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332 and the Class  
11 Action Fairness Act. Venue is proper in this Court because a substantial part of the events or  
12 omissions giving rise to the claim occurred in this District, particularly in the City and County of San  
13 Francisco.

14 21. At all times relevant hereto, Merck & Co., Inc. was engaged in the business of  
15 manufacturing, marketing, promoting, selling, and/or distributing Vytorin®.

16 22. At all times relevant hereto, Schering-Plough Corporation was engaged in the business  
17 of manufacturing, marketing, promoting, selling, and/or distributing Vytorin®.

18 23. Merck & Co., Inc. placed defective Vytorin® into the stream of interstate and  
19 worldwide commerce.

20 24. Schering-Plough Corporation placed defective Vytorin® into the stream of interstate  
21 and worldwide commerce.

22 25. As a direct and proximate result of Merck & Co., Inc. placing Vytorin® into stream of  
23 commerce, Plaintiff and the class members have suffered and continue to suffer monetary damages,  
24 and will continue to suffer such damages indefinitely.

25 26. As a direct and proximate result of Schering-Plough Corporation placing Vytorin®  
26 into stream of commerce, Plaintiff and the class members have suffered and continue to suffer  
27 monetary damages, and will continue to suffer such damages indefinitely.  
28



1           27. Plaintiff and class members have incurred and will incur significant financial  
2 damages.

3           28. Upon information and belief, at all relevant times, Merck & Co. Inc., was present and  
4 doing business in the State of California and in the Northern District of California, County and City  
5 of San Francisco, in particular.

6           29. At all relevant times, Merck & Co., Inc. transacted, solicited, and conducted business  
7 in the State of California and derived substantial revenue from such business.

8           30. At all relevant times, Merck & Co., Inc. expected or should have expected that its acts  
9 would have consequences within the State of California, and the Northern District of California,  
10 County and City of San Francisco, in particular.

11           31. Upon information and belief, at all relevant times, Schering-Plough Corporation was  
12 present and doing business in the State of California and in the Northern District of California,  
13 County and City of San Francisco, in particular.

14           32. At all relevant times, Schering-Plough Corporation transacted, solicited, and  
15 conducted business in the State of California and derived substantial revenue from such business.

16           33. At all relevant times, Schering-Plough Corporation expected or should have expected  
17 that its acts would have consequences within the State of California, and the Northern District of  
18 California, County and City of San Francisco, in particular.

19                                   **INTRADISTRICT ASSIGNMENT**

20           34. On information and belief, a substantial part of the events or omissions which give rise  
21 to the claim occurred in the County and City of San Francisco.

22                                   **PARTIES**

23           35. Plaintiff, RICHARD HASKIN, is and was at all times hereinafter mentioned, a citizen  
24 of the United States of America, and resides in the State of California.

25           36. From in or about February 2005 until in or about January 2008, Plaintiff Richard  
26 Haskin purchased and used Vytarin<sup>®</sup> and as such, Plaintiff, Richard Haskin is a member of the  
27 proposed Class herein.  
28

1 37. Defendant Merck & Co., Inc. is a publicly traded corporation, duly formed and  
2 existing under and by the virtue of the laws of the State of New Jersey, with its principal place of  
3 business located at One Merck Drive, Whitehouse Station, New Jersey 08889.

4 38. Defendant Schering-Plough Corporation is a corporation, duly formed and existing  
5 under and by the virtue of the laws of the State of New Jersey, with its principal place of business  
6 located at 2000 Galloping Hill Road, Kenilworth, New Jersey 07033.

7 **FACTUAL ALLEGATIONS**

8 39. Vytorin<sup>®</sup> is a combination drug product comprised of two approved lipid-altering  
9 drugs, ezetimibe (Zetia<sup>®</sup>) and simvastatin (Zocor<sup>®</sup>) and was approved for market by the FDA on July  
10 23, 2004.

11 40. Vytorin<sup>®</sup> is marketed as a cholesterol reducer frequently prescribed as additional  
12 therapy for patients whose cholesterol remains high even after taking statins.

13 41. Zetia<sup>®</sup> inhibits the intestinal absorption of cholesterol and was approved for market by  
14 the FDA in 2002 for the treatment of primary hyperlipidemia. Zocor<sup>®</sup> is an HMG-CoA reductase  
15 inhibitor which blocks the rate-limiting enzyme in cholesterol synthesis that has been on the market  
16 since 1991.

17 42. Vytorin<sup>®</sup>'s New Drug Application (hereinafter "NDA") was submitted to the FDA on  
18 September 24, 2003 with fourteen clinical studies, including two clinical studies from the Zetia<sup>®</sup>  
19 NDA.

20 43. Of the fourteen clinical studies submitted to the FDA only two were relied upon for  
21 Vytorin<sup>®</sup>'s indication for treatment of primary hypercholesterolemia. One of the two studies (P680)  
22 accounts for 43% of the study participants in the two studies. P680 was a clinical trial from the  
23 Zetia<sup>®</sup> NDA. This means that Vytorin<sup>®</sup>'s indication for the treatment of primary  
24 hypercholesterolemia is based on only one (1) clinical trial consisting of only eight hundred and  
25 eighty seven (887) study participants.

1           44. The FDA relied primarily on the proven efficacy of Zetia<sup>®</sup> and Zocor<sup>®</sup> for its approval  
2 of Vytorin<sup>®</sup>'s indication for the treatment of primary hyperlipidemia and not data from study  
3 participants taking Vytorin<sup>®</sup>.

4           45. Clinical Study P038 was the only clinical efficacy study out of fourteen clinical trials  
5 that used the to-be-marketed formulation of Vytorin<sup>®</sup> and it was not used to support Vytorin<sup>®</sup>'s  
6 indication for the treatment of primary hypercholesterolemia.

7           46. The trial known as ENHANCE (Ezetimibe and Simvastatin in Hyperlipidemia  
8 Enhances Atherosclerosis Regression) began in June 2002 and ended in April 2006.

9           47. The ENHANCE study compared Vytorin<sup>®</sup> 80 with Zocor<sup>®</sup> alone.

10          48. Zocor<sup>®</sup> alone is widely believed by the medical community to reduce arterial intima-  
11 media thickness.

12          49. The intima-media of an artery can become thick thereby restricting blood flow. This  
13 process is known as atherosclerosis. The thickening of the intima-media is caused by a buildup of  
14 plaque.

15          50. The ENHANCE study was unlike previous Vytorin<sup>®</sup> studies in that the primary  
16 endpoint was to measure the change in ultrasound-determined average carotid artery intima-media  
17 thickness (IMT) on a per subject basis between baseline and endpoint.

18          51. All the study participants in the ENHANCE study patients had been treated and their  
19 arteries measured by April 2006. Cardiologists expected to see results of ENHANCE at a medical  
20 conference in November, 2006 then at another in March, 2007. Defendants recently announced that  
21 they will present the data with a new primary endpoint at the American College of Cardiology  
22 Conference in March, 2008.

23          52. In response to Schering-Plough Corporation's announcement that they will present the  
24 data at the American College of Cardiology Conference in March, 2008 with a new primary  
25 endpoint, on December 11, 2007, Congress launched an investigation into the delay in Defendants  
26 reporting the ENHANCE study data.

53. Defendants did not register ENHANCE in the government clinical trial database  
www.clinicaltrials.gov until approximately one year after April, 2006.

54. Upon information and belief, Defendants were aware at least as early as April, 2006  
that Vytorin<sup>®</sup> failed to slow the accumulation of fatty plaque in the arteries.

55. Upon information and belief, Merck & Co., Inc. was aware at least as early as April,  
2006, that Vytorin<sup>®</sup> contributed to plaque formation over Zocor.

56. Upon information and belief, Merck & Co., Inc. was aware at least as early as April,  
2006, that Vytorin<sup>®</sup> raised the risk of myocardial infarction and cerebral vascular accidents in  
patients taking Vytorin<sup>®</sup>.

57. Upon information and belief, Schering-Plough Corporation was aware at least as early  
as April, 2006 that Vytorin<sup>®</sup> failed to slow the accumulation of fatty plaque in the arteries.

58. Upon information and belief, Schering-Plough Corporation was aware at least as early  
as April, 2006, that Vytorin<sup>®</sup> contributed to plaque formation.

59. Upon information and belief, Schering-Plough Corporation was aware at least as early  
as April, 2006, that Vytorin<sup>®</sup> raised the risk of myocardial infarction and cerebral vascular accidents  
in patients taking Vytorin<sup>®</sup>.

60. Merck & Co., Inc. recklessly failed to disclose that Vytorin<sup>®</sup> was ineffective for the  
treatment of high-cholesterol and continued to sell Vytorin<sup>®</sup> with this knowledge.

61. Merck & Co., Inc. intentionally failed to disclose that Vytorin<sup>®</sup> was ineffective for the  
treatment of high-cholesterol and continued to sell Vytorin<sup>®</sup> with this knowledge.

62. Schering-Plough Corporation recklessly failed to disclose that Vytorin<sup>®</sup> was  
ineffective for the treatment of high-cholesterol and continued to sell Vytorin<sup>®</sup> with this knowledge.

63. Schering-Plough Corporation intentionally failed to disclose that Vytorin<sup>®</sup> was  
ineffective for the treatment of high-cholesterol and continued to sell Vytorin<sup>®</sup> with this knowledge.

64. Defendants knew, or had reason to know, of the defect in Vytorin<sup>®</sup> at least as early as  
April, 2006. This knowledge was concealed from Plaintiff, Plaintiff Class members, the medical  
community, and the public at large.



65. Defendants' dangerous and careless conduct of concealment, equates to conduct purposely committed, without regard for the rights and safety of the Plaintiff and members of the Class.

#### **CLASS DEFINITION**

66. Plaintiff brings this action pursuant to Federal Rules of Civil Procedure Rule 23 on behalf of himself, and all others similarly situated, including the class defined as follows:

**Vytorin® Class:** All citizens, residents or domiciliaries of the State of California who are presently or have purchased Vytorin® and such citizens', residents' and domiciliaries' estates, representatives, administrators, spouses, children, relatives and "significant others" as their heirs or survivors.

67. Excluded from the Class are:

- a) Merck & Co., Inc.'s officers and directors;
- b) Schering-Plough Corporation's officers and directors;
- c) Any judge or judicial official assigned to this matter and his or her immediate family; and
- d) Any legal representative, successor, or assign of any excluded persons or entities.

#### **CLASS ACTION ALLEGATIONS**

68. Numerosity of the Class: The proposed Class is so numerous that joinder is impractical. The disposition of these claims through this class action will be more efficient and will benefit the parties and the Court. Some estimates place the number of patients taking Vytorin® in the "millions", but suffice to say there may be hundreds of thousands of members of the Class. The identities of the individual members of the class are ascertainable through, *inter alia*, medical and pharmaceutical records, as well as Class members may be informed of the pendency of this class action by direct mail, internet, or other means.

1           69. Predominance of Common Questions of Fact and Law: A well-defined community of  
2 interest in the questions of law and fact common to the Vytorin<sup>®</sup> Class predominate over questions  
3 affecting only individual class members including, but not limited to, the following:

- 4           a) Whether defendants failed to give adequate and timely warning of the dangers  
5           of the Vytorin<sup>®</sup>;
- 6           b) Whether Defendants concealed adverse information from Plaintiff and the  
7           Vytorin<sup>®</sup> Class regarding the testing and safety of the Vytorin<sup>®</sup>;
- 8           c) Whether Defendants violated California state consumer protection laws;
- 9           d) Whether Plaintiff and the Class members are entitled to recover compensatory,  
10           exemplary, punitive, and/or other damages as a result of Defendants' unlawful  
11           conduct;
- 12           e) What is the proper mechanism for assessing and awarding damages and  
13           administering other relief to the Class members, including relief to reduce the  
14           threat of future harm to Class members;
- 15           f) Whether Defendants designed, manufactured, and/or marketed a defective  
16           product;
- 17           g) Whether Defendants failed to address the safety concerns of Vytorin<sup>®</sup> shown in  
18           reports and/or studies;
- 19           h) Whether Defendants recklessly delayed reporting of the results of the  
20           ENHANCE clinical trial to the FDA, the medical community, pharmaceutical  
21           community, other regulatory authorities, the public, the Defendants herein and  
22           the Plaintiff class actions members;
- 23           i) whether Defendants intentionally delayed reporting of the results of the  
24           ENHANCE clinical trial to the FDA, the medical community, pharmaceutical  
25           community, other regulatory authorities, the public, the Defendants herein and  
26           the Plaintiff class actions members;
- 27
- 28

- j) Whether Defendants violated Federal statutes in not timely reporting the data from the ENHANCE study;
- k) Whether Defendants violated State regulations in not timely reporting the data from the ENHANCE study;
- l) Whether Defendants negligently, recklessly or intentionally concealed information about the safety and efficacy of Vytorin<sup>®</sup> from the Plaintiff and the Plaintiff Class, as well as their physicians, hospitals, and healthcare professionals;
- m) Whether Defendants watered down and/or diluted the actual risk of and safety concerns of Vytorin<sup>®</sup>;
- n) Whether Defendants under-reported the adverse events associated with Vytorin<sup>®</sup>;
- o) Whether Defendants' inadequately, improperly, negligently, recklessly, and/or fraudulently compared test results of the safety and/or efficacy of Vytorin<sup>®</sup> versus other available hyperlipidemia treatments;
- p) Whether Defendants' conduct constitutes fraudulent concealment;
- q) Whether Defendants' conduct constitutes negligence;
- r) Whether Defendants breached implied warranties of merchantability;
- s) Whether Defendants failed to adequately warn or notify consumers regarding the dangerous side effects, safety concerns, lack of efficacy of Vytorin<sup>®</sup>;
- t) Whether Defendants failed to test and/or failed to adequately test the Vytorin<sup>®</sup>, generally;
- u) Whether Plaintiff Class members have sustained irreparable harm and whether they are entitled to equitable relief including restitution and, if so, the nature and extent of such damages;
- v) Whether the Plaintiff Class is entitled to compensatory damages and, if so, the nature and extent of such damages;

- 1 w) Whether Defendant is liable for punitive damages, and if so, how much is  
2 necessary and appropriate to punish them for their conduct, deter others and  
3 fulfill the policies and purposes of punitive and/or exemplary damages;  
4 x) How any and all punitive and/or exemplary damages awarded to Plaintiff  
5 should be equitably allocated among the Plaintiff and the Plaintiff Class;  
6 y) Whether Defendants acted to defraud, misrepresent, and deceive the Plaintiff  
7 and/or the Plaintiff Class;  
8 z) Whether Defendants failed to adequately test their products;  
9 aa) Whether Defendants failed to adequately reveal the results, if any, that were  
10 yielded by the testing of their product to the Plaintiff, Plaintiff Class, their  
11 physicians, hospitals, and other healthcare professionals;  
12 bb) Whether Defendants failed to adequately warn of the side effects and safety  
13 concerns of Vytorin<sup>®</sup>, and/or supplement its warnings as it discovered new side  
14 effects and safety concerns revealed through the aforementioned tests, studies,  
15 and/or reports;  
16 cc) Whether Defendants failed to adequately warn of the side effects and safety  
17 concerns of Vytorin<sup>®</sup>, and/or supplement its warnings as they discovered new  
18 side effects and safety concerns that Vytorin<sup>®</sup> caused because of  
19 underreporting, underestimating, and/or downplaying the serious and dangerous  
20 side effects of Vytorin<sup>®</sup>.

21 70. Typicality: Having been a victim of Defendants' unlawful conduct, Plaintiff is a  
22 member of the Vytorin<sup>®</sup> Class. Plaintiff purchased and ingested Vytorin<sup>®</sup>. All members of the class  
23 have purchased and ingested Vytorin<sup>®</sup>. Plaintiff and members of the Vytorin<sup>®</sup> Class have similarly  
24 suffered harm arising from Defendants' violations of law, as alleged herein.

25 71. Adequacy of Representation: Plaintiff is an adequate representative of the Plaintiff  
26 Class because he is a member of the Plaintiff Class and his interests do not conflict with the interests  
27 of the members of the Plaintiff Class he seeks to represent. Further, Plaintiff is represented by  
28



1 experienced and able counsel who have litigated numerous other mass torts and products liability  
2 class actions, and they intend to prosecute this action vigorously for the benefit of the entire Plaintiff  
3 Class. Plaintiff and his counsel will fairly and adequately protect the interests of the members of the  
4 Plaintiff Class.

5 72. Superiority: A class action is superior to other available methods for the efficient  
6 adjudication of this litigation since individual litigation of each Class members' claims is  
7 impracticable. It would be unduly burdensome to the courts in which individual litigations would  
8 proceed. Further, individual litigations present a potential for inconsistent and/or contradictory  
9 judgments and further increases the delay and expense to all parties and the courts. By contrast, the  
10 class action device presents far fewer management difficulties and provides the benefit of a single  
11 adjudication, economies of scale, and comprehensive supervision by a single court. Additionally,  
12 notice of the pendency and/or resolution of this class action can be provided to Class members by  
13 direct mail, as upon information and belief, Defendants herein have kept detailed records as to their  
14 sale of Vytorin®.

15 73. This action is also properly certified under the provisions of Federal Rule of Civil  
16 Procedure Rule 23 because:

- 17 a) The prosecution of separate actions by individual members of the Class would  
18 create a risk of inconsistency of varying adjudications with respect to individual  
19 Class members, thus establishing incompatible standards of conduct for  
20 Defendants' financing activities;
- 21 b) Due to the nature of the relief sought, the prosecution of separate actions by the  
22 individual members of the Class would create a risk of adjudications with  
23 respect to them that would as a practical matter, be dispositive of the interests  
24 of the other members of the Class not parties to such adjudications or would  
25 substantially impair or impede the ability of such members of the Class to  
26 protect their interests; and
- 27  
28

c) By failing to make the written disclosures required by applicable laws, Defendants have and acted or refused to act in respects generally applicable to the Class, thereby making appropriate final injunctive relief with regard to the members of the Class as a whole in terms of the nature of the relief sought.

**EQUITABLE TOLLING OF APPLICABLE STATUTES OF LIMITATIONS**

74. The running of any statute of limitations has been tolled by reason of Defendants' fraudulent concealment. Defendants, through suppressing reports, failing to follow through on FDA notification requirements, failing to disclose a known defect to physicians or Class members, and misrepresenting their product as safe for intended use, actively concealed from Plaintiff, the Class, Plaintiff's and the Class's prescribing physicians the true risks associated with Vytorin®.

75. As a result of Defendants' actions, Plaintiff, and the Class, and their prescribing physicians were unaware, and could not reasonably know or have learned through reasonable diligence that Plaintiff and Class members had been exposed to the risks alleged herein and that those risks were the direct and proximate result of Defendants' acts and omissions.

76. Furthermore, defendants are estopped from relying on any statute of limitations because of their fraudulent concealment of the true character, quality and nature of Vytorin®. Defendants were under a duty to disclose the true character, quality and nature of Vytorin® because this was non-public information over which the Defendants had and continues to have exclusive control, and because Defendants knew that this information was not available to the Plaintiff and Class members, medical providers and/or to their facilities. In addition, the Defendants are estopped from relying on any statute of limitations because of their concealment of these facts.

77. Plaintiff and the Class had no knowledge that Defendants were engaged in the wrongdoing alleged herein. Because of the fraudulent acts of concealment of wrongdoing by the Defendants, the Plaintiff and the Class could not have reasonably discovered the wrongdoing at any time prior to January 15, 2008. Also, the economics of this fraud should be considered. Defendants had the ability to and did spend enormous amounts of money in furtherance of their purpose of marketing and promoting a profitable drug, notwithstanding the risks about which they were aware.

1 Plaintiff and the Class and medical professionals could not have afforded and could not have possibly  
2 conducted studies to determine the nature, extent and identity of related health risks, and were forced  
3 to rely on only the Defendants' representations.

4  
5 **FIRST CAUSE OF ACTION**  
**(FRAUDULENT CONCEALMENT)**

6 78. Plaintiff, RICHARD HASKIN, individually, and on behalf of all others similarly  
7 situated, repeats, reiterates and re-alleges each and every allegation of this Complaint in each of the  
8 foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

9 79. At all times during the course of dealing between Defendants and Plaintiff, members  
10 of the Plaintiff Class and/or Plaintiffs' healthcare providers, Defendants misrepresented the safety of  
11 Vytorin®.

12 80. At all times during the course of dealing between Defendants and Plaintiff,  
13 RICHARD HASKIN, members of the Plaintiff Class and/or Plaintiff's healthcare providers,  
14 Defendants misrepresented the efficacy of Vytorin® in that the product fails to reduce total  
15 cholesterol, low-dense lipoprotein (LDL) cholesterol and triglyceride levels while simultaneously  
16 raising high-dense lipoprotein cholesterol levels and accelerates atherosclerosis.

17 81. Defendants knew or were reckless in not knowing that its representations were false.

18 82. Defendant fraudulently concealed and/or intentionally omitted the following material  
19 information: that Vytorin® is not as safe as other available antihyperlipidemia medications and that  
20 Vytorin® lacks any established and/or known efficacy.

21 83. Defendant fraudulently concealed and/or intentionally omitted the following material  
22 information: that the risks of adverse events with Vytorin® are higher than those with other available  
23 antihypercholesterolemia medications.

24 84. Defendants fraudulently concealed and/or intentionally omitted the following  
25 material information: that the risks of adverse events with the Vytorin® were not adequately tested for  
26 and/or known by Defendants.

1           85. Defendants fraudulently concealed and/or intentionally omitted the following  
2 material information: that Defendants were aware of dangers of Vytorin<sup>®</sup>, in addition to and above  
3 and beyond those associated with other anticholesterolemia medications.

4           86. Defendants fraudulently concealed and/or intentionally omitted the following  
5 material information: that Vytorin<sup>®</sup> is defective, and it causes dangerous side effects, including but  
6 not limited to, acceleration of the process of atherosclerosis, failure to reduce total cholesterol levels,  
7 LDL cholesterol levels and triglycerides while simultaneously increase HDL cholesterol levels, and  
8 the induction of myocardial infarction and/or cerebral vascular accidents, and/or other severe and  
9 permanent health consequences, in a much more and significant rate than other available  
10 anticholesterolemia medications.

11           87. Defendants fraudulently concealed and/or intentionally omitted the following  
12 material information: that the results of the aforementioned ENHANCE study shows that Vytorin<sup>®</sup>  
13 accelerates the process of atherosclerosis and/or fails to reduce total cholesterol levels, LDL  
14 cholesterol levels and triglycerides while simultaneously increasing HDL cholesterol levels.

15           88. Defendants fraudulently concealed and/or intentionally omitted the following  
16 material information: that patients needed to be monitored more regularly than normal while using  
17 Vytorin<sup>®</sup>.

18           89. Defendants were under a duty to disclose to Plaintiff, RICHARD HASKIN, members  
19 of the Plaintiff Class and/or their physicians, hospitals, and healthcare providers the aforementioned  
20 as it pertains to Vytorin<sup>®</sup>.

21           90. Defendants had sole access to material facts concerning the defective nature of the  
22 product and its propensity to cause damage and injury to users of Vytorin<sup>®</sup>, including the Plaintiff,  
23 RICHARD HASKIN, and members of the Plaintiff Class.

24           91. Defendants' concealment and omissions of material facts concerning, inter alia, the  
25 safety and/or efficacy of Vytorin<sup>®</sup> was made purposefully, willfully, wantonly, and/or recklessly, to  
26 mislead Plaintiff- RICHARD HASKIN, members of the Plaintiff Class and/or their physicians,  
27  
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1 hospitals and/or healthcare providers into reliance, continued use of Vytorin<sup>®</sup>, and actions thereon,  
2 and to cause them to purchase, recommend, dispense and/or use Vytorin<sup>®</sup>.

3 92. Defendants concealment and omissions of material facts concerning, *inter alia*, the  
4 safety and/or efficacy of Vytorin<sup>®</sup> was made purposefully, willfully, wantonly, and/or recklessly, to  
5 mislead Plaintiff, RICHARD HASKIN, members of the Plaintiff Class and/or their physicians,  
6 hospitals and/or healthcare providers into reliance, continued use of Vytorin<sup>®</sup>, and actions thereon,  
7 and to cause them to purchase, recommend, dispense and/or use Vytorin<sup>®</sup>, solely for their financial  
8 gain and without regard for the safety of their customers, the Plaintiffs herein and the Plaintiff class  
9 action members.

10 93. Defendants knew that Plaintiff, RICHARD HASKIN, members of the Plaintiff Class  
11 and/or their physicians, hospitals and healthcare providers had no way to determine the truth behind  
12 Defendants' concealment and omissions, and that these included material omissions of facts  
13 surrounding Vytorin<sup>®</sup>, as set forth herein.

14 94. Plaintiff, as well as his doctors, healthcare providers, and/or hospitals reasonably  
15 relied on facts revealed which negligently, fraudulently and/or purposefully did not include facts that  
16 were concealed and/or omitted by Defendant.

17 95. By reason of the foregoing Plaintiff and Plaintiff Class experienced and/or are at risk  
18 of experiencing serious and dangerous side effects, as well as have incurred financial damage and  
19 injury.

20 **SECOND CAUSE OF ACTION**  
21 **(VIOLATION OF CALIFORNIA BUSINESS AND**  
22 **PROFESSIONS CODE §17200, et seq)**

23 96. Plaintiff, on behalf of himself and all others similarly situated, repeats, reiterates,  
24 realleges each and every allegation contained in this Complaint with the same force and effect as if  
25 fully set forth herein.

26 97. Defendants misrepresented and omitted material information regarding Vytorin<sup>®</sup> by  
27 failing to disclose known risks.  
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1           98. Defendants' misrepresentations and concealment of material facts constitute  
 2           unconscionable commercial practices, deception, fraud, false pretenses, misrepresentation, and/or the  
 3           knowing concealment, suppression, or omission of materials facts with the intent that others rely on  
 4           such concealment, suppression, or omission in connection with the sale and advertisement of  
 5           Vytorin® in violation of California Business and Professions Code Section 17200 *et seq.*

6           99. Plaintiff is informed and believes and thereon alleges that Defendants engaged in  
 7           unlawful, unfair, and/or fraudulent business acts and practices and engaged in unfair, deceptive,  
 8           untrue and/or misleading advertising by, *inter alia*:

- 9                   a) Manufacturing, marketing and selling Vytorin®, despite the fact that
- 10                   defendants knew or should have known that Vytorin® is not efficacious in
- 11                   managing hyperlipidemia thereby placing patients at an increased risk of
- 12                   accelerating or worsening cardiovascular disease, which could result in
- 13                   myocardial infarction or cerebral vascular accident;
- 14                   b) Manufacturing, marketing and selling Vytorin®, despite the fact that Vytorin®
- 15                   is no better at reducing artery clogging than older and/or less expensive drugs;
- 16                   c) Marketing Vytorin® as safe and effective;
- 17                   d) Concealing from consumers the fact that Vytorin® increased the intima-media
- 18                   thickness (IMT) of the clinical trial participants that used Vytorin® as
- 19                   compared to the clinical trial participants that used Zocor;
- 20                   e) In the course of doing business, knowingly and intentionally exposing the Class
- 21                   Members to increased risk of accelerating or worsening cardiovascular disease.

22           100. Defendants' acts and omissions as set forth above were and are unfair, unlawful,  
 23           misleading, likely to deceive the consuming public, and engaged in with the intent to directly or  
 24           indirectly induce members of the public to purchase Vytorin®.

25           101. Plaintiffs have no adequate remedy at law and will suffer irreparable injury in that  
 26           Defendants will continue or will recommence engaging in unfair business practices and will continue  
 27           or will recommence disseminating untrue and misleading advertising in violation of Section 17500, *et*  
 28

1 *seq.* of the Business & Professions Code, and will refuse to notify consumers of the inefficacy of  
 2 Vytorin®, unless and until appropriate injunctions are issued by this Court.

3 102. This action seeks to enforce an important right affecting the public interest by  
 4 insuring that advertisements and marketing of Vytorin® are accurate and not misleading to the  
 5 consuming public. Consequently, Plaintiffs should be awarded attorneys' fees and costs for pursuit  
 6 of this public interest, pursuant to Cal. Civ. Pro, § 1021.5.

7 **THIRD CAUSE OF ACTION**  
 8 **(VIOLATION OF CONSUMERS LEGAL REMEDIES ACT)**

9 103. Plaintiff, on behalf of himself and all others similarly situated, repeats, reiterates,  
 10 realleges each and every allegation contained in this Complaint with the same force and effect as if  
 11 fully set forth herein.

12 104. This Complaint is filed and these proceedings are instituted, pursuant to California  
 13 Civil Code section 1750, *et seq.*, commonly referred to as the Consumers Legal Remedies Act  
 14 ("CLRA"), to obtain injunctive relief, restitution, any other relief this Court deems proper, and  
 15 attorneys' fees from Defendants.

16 105. Among others, Defendants' conduct is in violation of California Civil Code  
 17 section 1770(5), 1770(7) and 1770(9). Defendants' acts and business practices constitute unlawful  
 18 methods of competition and unfair or deceptive acts within the meaning of California Civil Code  
 19 section 1750, *et seq.*, including but not limited to the following:

- 20 a) Marketing, promoting or selling Vytorin® as safer or superior to other brands  
 21 of hyperlipidemia medications when it is not, and when Vytorin® increased the  
 22 intima-media thickness (IMT) of the clinical trial participants that used  
 23 Vytorin® as compared to the clinical trial participants that used Zocor; and  
 24 b) Marketing, promoting or selling Vytorin® as efficacious in managing  
 25 hyperlipidemia when in fact its use put patients at risk of accelerating the  
 26 advancement of cardiovascular disease.

106. Plaintiffs are entitled to injunctive relief, restitution, any other relief this Court deems proper, and attorneys' fees from Defendants as a result of such acts or practices.

107. The illegal conduct alleged herein is continuing and there is no indication that Defendants will refrain from such activity in the future.

**FOURTH CAUSE OF ACTION**  
**(UNJUST ENRICHMENT)**

108. Plaintiff, on behalf of himself and all others similarly situated, repeats, reiterates, realleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

109. Plaintiff is informed and believes and thereon alleges that Defendants received profits in connection with the manufacture and sale of Vytorin®.

110. Plaintiff and each Class Member purchased Vytorin® believing that Vytorin® was a safe and effective medication for treating hyperlipidemia, and superior to other medications for treating hyperlipidemia, and would not have purchased Vytorin® had they known the truth.

111. In truth, the use of Vytorin® placed Plaintiff and each member of the class at increased risk. Defendants concealed this fact from Plaintiff and each Class Member.

112. Defendants have therefore been unjustly enriched through the sale of Vytorin®.

**FIFTH CAUSE OF ACTION**  
**(BREACH OF IMPLIED WARRANTY)**

113. Plaintiff, RICHARD HASKIN, individually, and on behalf of all others similarly situated, repeats, reiterates and re-alleges each and every allegation of this Complaint in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

114. At all times herein mentioned, the Defendants manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold the Vytorin® for the treatment of hyperlipidemia.

115. At the time Defendants marketed, sold, and distributed Vytorin® for use by Plaintiff, RICHARD HASKIN, and members of the Plaintiff Class, Defendants knew of the use for



1 which Vytorin<sup>®</sup> was intended and impliedly warranted the product to be of merchantable quality and  
2 safe and fit for such use.

3 116. The Defendants impliedly represented and warranted to the Plaintiff, RICHARD  
4 HASKIN, and members of the Plaintiff Class and/or their physicians or healthcare providers that  
5 Vytorin<sup>®</sup> was safe and of merchantable quality and fit for the ordinary purpose for which said product  
6 was to be used.

7 117. That said representations and warranties aforementioned are false, misleading,  
8 and inaccurate in that Vytorin<sup>®</sup> is unsafe, unreasonably dangerous, improper, not of merchantable  
9 quality, and defective.

10 118. Plaintiff, RICHARD HASKIN, members of the Plaintiff Class and/or members of  
11 the medical community and/or healthcare professionals did rely on said implied warranty of  
12 merchantability of fitness for a particular use and purpose.

13 119. Plaintiff, RICHARD HASKIN, members of the Plaintiff Class and/or their  
14 physicians and/or healthcare professionals reasonably relied upon the skill and judgment of  
15 Defendants as to whether Vytorin<sup>®</sup> is of merchantable quality and safe and fit for its intended use.

16 120. Vytorin<sup>®</sup> was injected into the stream of commerce by the Defendants in a  
17 defective, unsafe, and inherently dangerous condition and the products and materials were expected  
18 to and did reach users, handlers, and persons coming into contact with said product without  
19 substantial change in the condition in which they were sold.

20 121. The Defendants herein breached the aforesaid implied warranties, as Vytorin<sup>®</sup>  
21 was not fit for its intended purposes and uses.

22 122. By reason of the foregoing Plaintiff and Plaintiff Class experienced and/or are at  
23 risk of experiencing serious and dangerous side effects, as well as have incurred financial damage  
24 and injury.

25 123. As a result of the foregoing acts and omissions the Plaintiff and Plaintiff Class  
26 requires and/or will require more health care and services and did incur medical, health, incidental  
27 and related expenses. Plaintiff and Plaintiff Class are informed and believe and further allege that the  
28

1 Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and  
2 services.

3 **PRAYER FOR RELIEF**

4 **WHEREFORE**, Plaintiff and members of Class demand judgment against Merck & Co., Inc.  
5 and Schering-Plough Corporation as follows:

- 6 1. An order certifying the Class, appointing Plaintiff as class representative, and  
7 appointing LEVIN SIMES KAISER and GORNICK LLP as counsel to the Class;
- 8 2. For an injunction prohibiting Defendants from engaging in the following conduct  
9 which violates the CLRA:
  - 10 a) Marketing, promoting or selling Vytorin® as safer or superior to other brands  
11 of hyperlipidemia medications when it is not, and when Vytorin® increased  
12 the intima-media thickness (IMT) of the clinical trial participants that used  
13 Vytorin® as compared to the clinical trial participants that used Zocor; and
  - 14 b) Marketing, promoting or selling Vytorin® as efficacious in managing  
15 hyperlipidemia when in fact its use put patients at risk of accelerating the  
16 advancement of cardiovascular disease.
- 17 3. Damages in an amount to be determined at trial;
- 18 4. Pre judgment and post judgment interest at the maximum rate allowable at law;
- 19 5. Exemplary and/or punitive damages in an amount to be determined at trial;
- 20 6. The costs and disbursements incurred by Plaintiff and Class members in  
21 connection with this action, including reasonable attorneys' fees;
- 22 7. All statutory damages;
- 23 8. Disgorgement of Defendants' profits from the sale Vytorin®;

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LEVIN SIMES KAISER & GORNICK LLP

By: Debra DeCarli  
Debra DeCarli, Esq.